

2016 West Virginia Laws Ch. 192 (S.B. 454)

WEST VIRGINIA 2016 SESSION LAWS

2016 REGULAR SESSION

Additions and deletions are not identified in this document.

Vetoed are indicated by ~~Text~~ ;
stricken material by ~~Text~~ .

Ch. 192 (S.B. No. 454)

West's No. 143

SUBSTANCE ABUSE—MEDICAL ASSISTANCE—TREATMENT

AN ACT to amend and reenact § 16-1-4 of the Code of West Virginia, 1931, as amended; to amend said code by adding thereto a new article, designated § 16-5Y-1, § 16-5Y-2, § 16-5Y-3, § 16-5Y-4, § 16-5Y-5, § 16-5Y-6, § 16-5Y-7, § 16-5Y-8, § 16-5Y-9, § 16-5Y-10, § 16-5Y-11, § 16-5Y-12 and § 16-5Y-13; and to amend and reenact § 60A-9-4, § 60A-9-5, § 60A-9-5a, § 60A-9-7 and § 60A-9-8 of said code, all relating to regulation of medication-assisted treatment programs for substance use disorders; repealing regulation of opioid treatment programs; setting out purpose; providing definitions; creating licenses for opioid treatment programs; creating categories of licenses; setting out licensing requirements; providing for registration of office-based medication-assisted programs; providing for application, fees and inspections of office-based medication-assisted programs; setting operational requirements for medication-assisted treatment programs; providing for a program sponsor and medical director; setting forth staffing requirements; providing for regulation by Office of Health Facility Licensure and Certification; designating necessity for a medical director; prescribing minimum qualifications for a medical director; allowing enrollment as a Medicaid provider; providing billing requirements; setting forth minimum certification requirements; mandating state and federal criminal background checks; designating who may prescribe and dispense medication-assisted treatment medications; setting certain minimum practice standards for any medication-assisted treatment program providing medication-assisted treatment medications; permitting the use of telehealth; requiring the Board of Pharmacy to make certain notifications; requiring the medication-assisted treatment program to have a drug testing program; requiring certain information be reported in the patients; medical record; setting certain minimum patient treatment standards for any medication-assisted treatment program; providing medication-assisted treatment medications; requiring review of the West Virginia Controlled Substances Monitoring Program database for each patient at least quarterly; setting compliance requirements for a medication-assisted treatment program; providing for patient protocols, treatment plans and profiles; allowing liquid methadone to be provided as allowed by legislative rule; setting notification requirements of operation changes; restricting location of medication-assisted treatment programs; allowing for waivers from certain standards; allowing for variances from certain standards; permitting inspection warrants; providing for an administrative review; providing an appeal process; allowing civil monetary penalties; designating license limitations for deviation for accepted practice or patient treatment standards; permitting the secretary to promulgate rules; permitting the secretary to promulgate emergency rules; providing advertisement requirements; continuing the moratorium on new opioid treatment programs; establishing state authority for medication-assisted treatment programs; establishing state oversight authority for medication-assisted treatment programs; mandating data collection; granting Office of Health Facility Licensure and Certification access to the West Virginia Controlled Substances Monitoring Program database for use in regulation of health facilities; requiring reporting when an opioid antagonist is dispensed by certain persons; clarifying statutory language related to seventy-two hour prescriptions; prohibiting licensing boards from issuing or reissuing licenses to practitioners who have not registered for the West Virginia Controlled Substances Monitoring Program database; establishing a civil penalties; providing exceptions to penalties; clarifying language related to the Fight Substance Abuse Fund; placing administrative authority over the Fight Substance Abuse Fund with the Bureau for Public Health; revising statutory language to use defined terms; reorganizing existing language; and creating a pilot program.

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Be it enacted by the Legislature of West Virginia:

That § 16–1–4 of the Code of West Virginia, 1931, as amended, be amended and reenacted; that said code be amended by adding thereto a new article designated § 16–5Y–1, § 16–5Y–2, § 16–5Y–3, § 16–5Y–4, § 16–5Y–5, § 16–5Y–6, § 16–5Y–7, § 16–5Y–8, § 16–5Y–9, § 16–5Y–10, § 16–5Y–11, § 16–5Y–12 and § 16–5Y–13; and that § 60A–9–4, § 60A–9–5, § 60A–9–5a, § 60A–9–7 and § 60A–9–8 of said code be amended and reenacted, all to read as follows:

CHAPTER 16. PUBLIC HEALTH.

ARTICLE 1. STATE PUBLIC HEALTH SYSTEM.

<< WV ST § 16–1–4 >>

§ 16–1–4. Proposal of rules by the secretary.

(a) The secretary may propose rules in accordance with the provisions of article three, chapter twenty-nine-a of this code that are necessary and proper to effectuate the purposes of this chapter. The secretary may appoint or designate advisory councils of professionals in the areas of hospitals, nursing homes, barbers and beauticians, postmortem examinations, mental health and intellectual disability centers and any other areas necessary to advise the secretary on rules.

(b) The rules may include, but are not limited to, the regulation of:

(1) Land usage endangering the public health: *Provided*, That no rules may be promulgated or enforced restricting the subdivision or development of any parcel of land within which the individual tracts, lots or parcels exceed two acres each in total surface area and which individual tracts, lots or parcels have an average frontage of not less than one hundred fifty feet even though the total surface area of the tract, lot or parcel equals or exceeds two acres in total surface area, and which tracts are sold, leased or utilized only as single-family dwelling units. Notwithstanding the provisions of this subsection, nothing in this section may be construed to abate the authority of the department to:

(A) Restrict the subdivision or development of a tract for any more intense or higher density occupancy than a single-family dwelling unit;

(B) Propose or enforce rules applicable to single-family dwelling units for single-family dwelling unit sanitary sewerage disposal systems; or

(C) Restrict any subdivision or development which might endanger the public health, the sanitary condition of streams or sources of water supply;

(2) The sanitary condition of all institutions and schools, whether public or private, public conveyances, dairies, slaughterhouses, workshops, factories, labor camps, all other places open to the general public and inviting public patronage or public assembly, or tendering to the public any item for human consumption and places where trades or industries are conducted;

(3) Occupational and industrial health hazards, the sanitary conditions of streams, sources of water supply, sewerage facilities and plumbing systems and the qualifications of personnel connected with any of those facilities, without regard to whether the supplies or systems are publicly or privately owned; and the design of all water systems, plumbing systems, sewerage systems, sewage treatment plants, excreta disposal methods and swimming pools in this state, whether publicly or privately owned;

(4) Safe drinking water, including:

(A) The maximum contaminant levels to which all public water systems must conform in order to prevent adverse effects on the health of individuals and, if appropriate, treatment techniques that reduce the contaminant or contaminants to a level which

will not adversely affect the health of the consumer. The rule shall contain provisions to protect and prevent contamination of wellheads and well fields used by public water supplies so that contaminants do not reach a level that would adversely affect the health of the consumer;

(B) The minimum requirements for: Sampling and testing; system operation; public notification by a public water system on being granted a variance or exemption or upon failure to comply with specific requirements of this section and rules promulgated under this section; record keeping; laboratory certification; as well as procedures and conditions for granting variances and exemptions to public water systems from state public water systems rules; and

(C) The requirements covering the production and distribution of bottled drinking water and may establish requirements governing the taste, odor, appearance and other consumer acceptability parameters of drinking water;

(5) Food and drug standards, including cleanliness, proscription of additives, proscription of sale and other requirements in accordance with article seven of this chapter as are necessary to protect the health of the citizens of this state;

(6) The training and examination requirements for emergency medical service attendants and emergency medical care technician-paramedics; the designation of the health care facilities, health care services and the industries and occupations in the state that must have emergency medical service attendants and emergency medical care technician-paramedics employed and the availability, communications and equipment requirements with respect to emergency medical service attendants and to emergency medical care technician-paramedics. Any regulation of emergency medical service attendants and emergency medical care technician-paramedics may not exceed the provisions of article four-c of this chapter;

(7) The health and sanitary conditions of establishments commonly referred to as bed and breakfast inns. For purposes of this article, "bed and breakfast inn" means an establishment providing sleeping accommodations and, at a minimum, a breakfast for a fee. The secretary may not require an owner of a bed and breakfast providing sleeping accommodations of six or fewer rooms to install a restaurant-style or commercial food service facility. The secretary may not require an owner of a bed and breakfast providing sleeping accommodations of more than six rooms to install a restaurant-type or commercial food service facility if the entire bed and breakfast inn or those rooms numbering above six are used on an aggregate of two weeks or less per year;

(8) Fees for services provided by the Bureau for Public Health including, but not limited to, laboratory service fees, environmental health service fees, health facility fees and permit fees;

(9) The collection of data on health status, the health system and the costs of health care;

(c) The secretary shall propose a rule for legislative approval in accordance with the provisions of article three, chapter twenty-nine-a of this code for the distribution of state aid to local health departments and basic public health services funds.

The rule shall include the following provisions:

Base allocation amount for each county;

Establishment and administration of an emergency fund of no more than two percent of the total annual funds of which unused amounts are to be distributed back to local boards of health at the end of each fiscal year;

A calculation of funds utilized for state support of local health departments;

Distribution of remaining funds on a per capita weighted population approach which factors coefficients for poverty, health status, population density and health department interventions for each county and a coefficient which encourages counties to merge in the provision of public health services;

A hold-harmless provision to provide that each local health department receives no less in state support for a period of four years beginning in the 2009 budget year.

The Legislature finds that an emergency exists and, therefore, the secretary shall file an emergency rule to implement the provisions of this section pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code. The emergency rule is subject to the prior approval of the Legislative Oversight Commission on Health and Human Resources Accountability prior to filing with the Secretary of State.

(d) The secretary may propose rules for legislative approval that may include the regulation of other health-related matters which the department is authorized to supervise and for which the rule-making authority has not been otherwise assigned.

Ch. 16 Art. 5Y

ARTICLE 5Y. MEDICATION-ASSISTED TREATMENT PROGRAM LICENSING ACT.

<< WV ST § 16-5Y-1 >>

§ 16-5Y-1. Purpose.

The purpose of this act is to establish licensing and registration requirements for facilities and physicians that treat patients with substance use disorders to ensure that patients may be lawfully treated by the use of medication and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders and comply with oversight requirements developed by the Department of Health and Human Resources. The Legislature recognizes the problem of substance use disorders in West Virginia and the need for quality, safe treatment of substance use disorders to adequately protect the people of West Virginia.

<< WV ST § 16-5Y-2 >>

§ 16-5Y-2. Definitions.

(a) "Addiction" means a primary, chronic disease of brain reward, motivation, memory and related circuitry. Dysfunction in these circuits leads to characteristic biological, psychological, social and spiritual manifestations, which is reflected in an individual pathologically pursuing reward or relief by substance use, or both, and other behaviors. Addiction is characterized by inability to consistently abstain; impairment in behavioral control; craving; diminished recognition of significant problems with one's behaviors; interpersonal problems with one's behaviors and interpersonal relationships; a dysfunctional emotional response; and as addiction is currently defined by the American Society of Addiction Medicine.

(b) "Administrator" means an individual designated by the governing body to be responsible for the day-to-day operation of the opioid treatment programs.

(c) "Advanced alcohol and drug abuse counselor" means an alcohol and drug abuse counselor who is certified by the West Virginia Certification Board for Addiction and Prevention Professionals who demonstrates a high degree of competence in the addiction counseling field.

(d) "Alcohol and drug abuse counselor" means a counselor certified by the West Virginia Certification Board for Addiction and Prevention Professionals for specialized work with patients who have substance use problems.

(e) "Biopsychosocial" means of, relating to, or concerned with, biological, psychological and social aspects in contrast to the strictly biomedical aspects of disease.

(f) “Center for Substance Abuse Treatment” means the center under the Substance Abuse and Mental Health Services Administration that promotes community-based substance abuse treatment and recovery services for individuals and families in the community and provides national leadership to improve access, reduce barriers and promote high quality, effective treatment and recovery services.

(g) “Controlled Substances Monitoring Program database” means the database maintained by the West Virginia Board of Pharmacy pursuant to section three, article nine, chapter sixty-a of this code that monitors and tracks certain prescriptions written or dispensed by dispensers and prescribers in West Virginia.

(h) “Director” means the Director of the Office of Health Facility Licensure and Certification.

(i) “Dispense” means the preparation and delivery of a medication-assisted treatment medication in an appropriately labeled and suitable container to a patient by a medication-assisted treatment program or pharmacist.

(j) “Governing body” means the person or persons identified as being legally responsible for the operation of the opioid treatment program. A governing body may be a board, a single entity or owner, or a partnership. The governing body must comply with the requirements prescribed in rules promulgated pursuant to this article.

(k) “Medical director” means a physician licensed within the State of West Virginia who assumes responsibility for administering all medical services performed by the medication-assisted treatment program, either by performing them directly or by delegating specific responsibility to authorized program physicians and health care professionals functioning under the medical director’s direct supervision and functioning within their scope of practice.

(l) “Medication-assisted treatment” means the use of medications and drug screens, in combination with counseling and behavioral therapies, to provide a holistic approach to the treatment of substance use disorders.

(m) “Medication-assisted treatment program” means all publicly and privately owned opioid treatment programs and office based medication-assisted treatment programs, which prescribe medication-assisted treatment medications and treat substance use disorders, as those terms are defined in this article.

(n) “Medication-assisted treatment medication” means any medication that is approved by the United States Food and Drug Administration under section 505 of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. § 355, for use in the treatment of substance use disorders that is an opioid agonist and is listed on the schedule of controlled substances in article two, chapter sixty-a of this code.

(o) “Office based medication-assisted treatment” means all publicly or privately owned medication-assisted treatment programs in clinics, facilities, offices or programs that treat individuals with substance use disorders through the prescription, administration or dispensing of a medication-assisted treatment medication in the form of a partial opioid agonist or other medication-assisted medication approved for use in office based medication-assisted treatment setting.

(p) “Opioid agonist” means substances that bind to and activate the opiate receptors resulting in analgesia and pain regulation, respiratory depression and a wide variety of behavioral changes. As used in this article, the term “opioid agonist” does not include partial agonist medications used as an alternative to opioid agonists in the treatment of opioid addiction.

(q) “Opioid treatment program” means all publicly or privately owned medication-assisted treatment programs in clinics, facilities, offices or programs that treat individuals with substance use disorders through on-site administration or dispensing of a medication-assisted treatment medication in the form of an opioid agonist or partial opioid agonist.

- (r) "Owner" means any person, partnership, association or corporation listed as the owner of a medication-assisted treatment program on the licensing or registration forms required by this article.
- (s) "Partial opioid agonist" means a Federal Drug Administration approved medication that is used as an alternative to opioid agonists for the treatment of substance use disorders and that binds to and activates opiate receptors, but not to the same degree as full agonists.
- (t) "Physician" means an individual licensed in this state to practice allopathic medicine or surgery by the West Virginia Board of Medicine or osteopathic medicine or surgery by the West Virginia Board of Osteopathic Medicine and that meets the requirements of this article.
- (u) "Prescriber" means a person authorized in this state, working within their scope of practice, to give direction, either orally or in writing, for the preparation and administration of a remedy to be used in the treatment of substance use disorders.
- (v) "Program sponsor" means the person named in the application for the certification and licensure of a opioid treatment program who is responsible for the administrative operation of the opioid treatment program, and who assumes responsibility for all of its employees, including any practitioners, agents or other persons providing medical, rehabilitative or counseling services at the program.
- (w) "Secretary" means the Secretary of the West Virginia Department of Health and Human Resources or his or her designee.
- (x) "State opioid treatment authority" means the agency or individual designated by the Governor to exercise the responsibility and authority of the state for governing the treatment of substance use disorders, including, but not limited to, the treatment of opiate addiction with opioid drugs.
- (y) "State oversight agency" means the agency or office of state government identified by the secretary to provide regulatory oversight of medication-assisted treatment programs on behalf of the State of West Virginia.
- (z) "Substance" means the following:
- (1) Alcohol;
 - (2) Controlled substances defined by section two hundred four, article two, chapter sixty-a; section two hundred six, article two, chapter sixty-a; section two hundred eight, article two, chapter sixty-a and section two hundred ten, article two, chapter sixty-a of this code; or
 - (3) Any chemical, gas, drug or medication consumed which causes clinically and functionally significant impairment, such as health problems, disability and failure to meet major responsibilities at work, school or home.
- (aa) "Substance Abuse and Mental Health Services Administration" means the agency under the United States Department of Health and Human Services responsible for the accreditation and certification of medication-assisted treatment programs and that provides leadership, resources, programs, policies, information, data, contracts and grants for the purpose of reducing the impact of substance abuse and mental or behavioral illness.
- (bb) "Substance use disorder" means patterns of symptoms resulting from use of a substance that the individual continues to take, despite experiencing problems as a result; or as defined in the most recent edition of the American Psychiatric Association's Diagnostic and Statistical Manual of Mental Disorders.

(cc) “Telehealth” means the mode of delivering health care services and public health via information and communication technologies to facilitate the diagnosis, consultation, treatment education, care management, and self-management of a patient's health care while the patient is at the originating site and the health car.

(dd) “Variance” means written permission granted by the secretary to a medication-assisted treatment program that a requirement of this article or rules promulgated pursuant to this article may be accomplished in a manner different from the manner set forth in this article or associated rules.

(dd) “Waiver” means a formal, time-limited agreement between the designated oversight agency and the medication-assisted treatment program that suspends a rule, policy or standard for a specific situation so long as the health and safety of patients is better served in the situation by suspension of the rule, policy or standard than by enforcement.

<< WV ST § 16-5Y-3 >>

§ 16-5Y-3. Opioid treatment programs to obtain license; application; fees and inspections.

(a) No person, partnership, association or corporation may operate an opioid treatment program without first obtaining a license from the secretary in accordance with the provisions of this article and the rules lawfully promulgated pursuant to this article.

(b) Any person, partnership, association or corporation desiring a license to operate an opioid treatment program in this state shall file with the Office of Health Facility Licensure and Certification an application in such form and with such information as the secretary shall prescribe and furnish accompanied by an application fee.

(c) The Director of the Office of Health Facility Licensure and Certification or his or her designee shall inspect each facility and review all documentation submitted with the application. The director shall then provide a recommendation to the secretary whether to approve or deny the application for a license. The secretary shall issue a license if the facility is in compliance with the provisions of this article and with the rules lawfully promulgated pursuant to this article.

(d) A license shall be issued in one of three categories:

(1) An initial twelve month license shall be issued to an opioid treatment program establishing a new program or service for which there is insufficient consumer participation to demonstrate substantial compliance with this article and with all rules promulgated pursuant to this article;

(2) A provisional license shall be issued when an opioid treatment program seeks a renewal license, or is an existing program as of the effective date of this article and is seeking an initial license, and the opioid treatment program is not in substantial compliance with this article and with all rules promulgated pursuant to this article, but does not pose a significant risk to the rights, health and safety of a consumer. It shall expire not more than six months from the date of issuance, and may not be consecutively reissued; or

(3) A renewal license shall be issued when an opioid treatment program is in substantial compliance with this article and with all rules promulgated pursuant to this article. A renewal license shall expire not more than one year from the date of issuance.

(e) At least sixty days prior to the license expiration date, an application for renewal shall be submitted by the opioid treatment program to the secretary on forms furnished by the secretary. A license shall be renewed if the secretary determines that the applicant is in compliance with this article and with all rules promulgated pursuant to this article. A license issued to one program location pursuant to this article is not transferrable or assignable. Any change of ownership of a licensed medication-assisted treatment program requires submission of a new application. The medication-assisted treatment program shall notify the secretary of any change in ownership within ten days of the change and must submit a new application within the time frame prescribed by the secretary.

(f) Any person, partnership, association or corporation that seeks to obtain or renew a license for an opioid treatment program in this state must submit to the secretary the following documentation:

- (1) Full operating name of the program as advertised;
- (2) Legal name of the program as registered with the West Virginia Secretary of State;
- (3) Physical address of the program;
- (4) Preferred mailing address for the program;
- (5) Email address to be used as the primary contact for the program;
- (6) Federal Employer Identification Number assigned to the program;
- (7) All business licenses issued to the program by this state, the state Tax Department, the Secretary of State and all other applicable business entities;
- (8) Brief description of all services provided by the program;
- (9) Hours of operation;
- (10) Legal Registered Owner Name — name of the person registered as the legal owner of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal owner separately, indicating the percentage of ownership;
- (11) Medical director's full name, medical license number, Drug Enforcement Administration registration number, and a list of all current certifications;
- (12) For each employee of the program, provide the following:
 - (A) Employee's role and occupation within the program;
 - (B) Full legal name;
 - (C) Medical license, if applicable;
 - (D) Drug Enforcement Administration registration number, if applicable;
 - (E) Drug Enforcement Administration identification number to prescribe buprenorphine for addiction, if applicable; and
 - (F) Number of hours per week worked at program;
- (13) Name and location address of all programs owned or operated by the applicant;
- (14) Notarized signature of applicant;
- (15) Check or money order for licensing fee and inspection fee;

- (16) Verification of education and training for all physicians, counselors and social workers practicing at or used by referral by the program such as fellowships, additional education, accreditations, board certifications and other certifications;
- (17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber practicing at the program for the three months preceding the date of application; and
- (18) If applicable, a copy of a valid Certificate of Need or a letter of exemption from the West Virginia Health Care Authority.
- (g) Upon satisfaction that an applicant has met all of the requirements of this article, the secretary shall issue a license to operate an opioid treatment program. An entity that obtains this license may possess, have custody or control of, and dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.
- (h) The opioid treatment program shall display the current license in a prominent location where services are provided and in clear view of all patients.
- (i) The secretary or his or her designee shall inspect on a periodic basis all opioid treatment programs that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.
- (j) Any license in effect at the time of the passage of this section in the 2016 regular session of the Legislature shall remain in effect until such time as new legislative rules promulgated pursuant to this article become effective. Upon the effective date of the new rules any licensee shall file for a new license within six months pursuant to the licensing procedures and requirements of this section and the new rules promulgated hereunder. The existing license shall remain effective until receipt of the new license.

<< WV ST § 16-5Y-4 >>

**§ 16-5Y-4. Office based medication-assisted treatment programs
to obtain registration; application; fees and inspections.**

- (a) No person, partnership, association or corporation may operate an office based medication-assisted treatment program without first obtaining a registration from the secretary in accordance with the provisions of this article and the rules lawfully promulgated pursuant to this article.
- (b) Any person, partnership, association or corporation desiring a registration to operate an office based medication-assisted treatment program in this state shall file with the Office of Health Facility Licensure and Certification an application in such form and with such information as the secretary shall prescribe and furnish accompanied by an application fee.
- (c) The Director of the Office of Health Facility Licensure and Certification or his or her designee shall inspect and review all documentation submitted with the application. The director shall then provide a recommendation to the secretary whether to approve or deny the application for registration. The secretary shall issue a registration if the facility is in compliance with the provisions of this article and with the rules lawfully promulgated pursuant to this article.
- (d) A registration shall be issued in one of three categories:
- (1) An initial twelve month registration shall be issued to an office based medication-assisted treatment program establishing a new program or service for which there is insufficient consumer participation to demonstrate substantial compliance with this article and with all rules promulgated pursuant to this article;
- (2) A provisional registration shall be issued when an office based medication-assisted treatment program seeks a renewal registration, or is an existing program as of the effective date of this article and is seeking an initial registration, and the office based medication-assisted treatment program is not in substantial compliance with this article and with all rules promulgated

pursuant to this article, but does not pose a significant risk to the rights, health and safety of a consumer. It shall expire not more than six months from the date of issuance, and may not be consecutively reissued; or

(3) A renewal registration shall be issued when an office based medication-assisted treatment program is in substantial compliance with this article and with all rules promulgated pursuant to this article. A renewal registration shall expire not more than one year from the date of issuance.

(e) At least sixty days prior to the registration expiration date, an application for renewal shall be submitted by the office based medication-assisted treatment program to the secretary on forms furnished by the secretary. A registration shall be renewed if the secretary determines that the applicant is in compliance with this article and with all rules promulgated pursuant to this article. A registration issued to one program location pursuant to this article is not transferrable or assignable. Any change of ownership of a registered medication-assisted treatment program requires submission of a new application. The medication-assisted treatment program shall notify the secretary of any change in ownership within ten days of the change and must submit a new application within the time frame prescribed by the secretary.

(f) Any person, partnership, association or corporation seeking to obtain or renew a registration for an office based medication-assisted treatment program in this state must submit to the secretary the following documentation:

- (1) Full operating name of the program as advertised;
- (2) Legal name of the program as registered with the West Virginia Secretary of State;
- (3) Physical address of the program;
- (4) Preferred mailing address for the program;
- (5) Email address to be used as the primary contact for the program;
- (6) Federal Employer Identification Number assigned to the program;
- (7) All business licenses issued to the program by this state, the state Tax Department, the Secretary of State and all other applicable business entities;
- (8) Brief description of all services provided by the program;
- (9) Hours of operation;
- (10) Legal Registered Owner Name — name of the person registered as the legal owner of the program. If more than one legal owner (i.e., partnership, corporation, etc.) list each legal owner separately, indicating the percentage of ownership;
- (11) Medical director's full name, medical license number, Drug Enforcement Administration registration number, and a listing of all current certifications;
- (12) For each physician, counselor or social worker of the program, provide the following:
 - (A) Employee's role and occupation within the program;
 - (B) Full legal name;

- (C) Medical license, if applicable;
- (D) Drug Enforcement Administration registration number, if applicable;
- (E) Drug Enforcement Administration identification number to prescribe buprenorphine for addiction, if applicable; and
- (F) Number of hours worked at program per week;
- (13) Name and location address of all programs owned or operated by the applicant;
- (14) Notarized signature of applicant;
- (15) Check or money order for registration fee;
- (16) Verification of education and training for all physicians, counselors and social workers practicing at or used by referral by the program such as fellowships, additional education, accreditations, board certifications and other certifications;
- (17) Board of Pharmacy Controlled Substance Prescriber Report for each prescriber practicing at the program for the three months preceding the date of application; and
- (18) If applicable, a copy of a valid Certificate of Need or a letter of exemption from the West Virginia Health Care Authority.
- (g) Upon satisfaction that an applicant has met all of the requirements of this article, the secretary shall issue a registration to operate an office based medication-assisted treatment program. An entity that obtains this registration may possess, have custody or control of, and dispense drugs indicated and approved by the United States Food and Drug Administration for the treatment of substance use disorders.
- (h) The office based medication-assisted treatment program shall display the current registration in a prominent location where services are provided and in clear view of all patients.
- (i) The secretary or his or her designee shall perform complaint and verification inspections on all office based medication-assisted treatment programs that are subject to this article and all rules adopted pursuant to this article to ensure continued compliance.
- (j) Any person, partnership, association or corporation operating a medication-assisted treatment program shall be permitted to continue operation until the effective date of the new rules promulgated pursuant to this article. At that time a person, partnership, association or corporation shall file for registration within six months pursuant to the licensing procedures and requirements of this section and the new rules promulgated hereunder. The existing procedures of the person, partnership, association or corporation shall remain effective until receipt of the registration.

<< WV ST § 16-5Y-5 >>

§ 16-5Y-5. Operational requirements.

- (a) The medication-assisted treatment program shall be licensed and registered in this state with the secretary, the Secretary of State, the state Tax Department and all other applicable business or licensing entities.
- (b) The program sponsor need not be a licensed physician but shall employ a licensed physician for the position of medical director, when required by the rules promulgated pursuant to this article.

(c) Each medication-assisted treatment program shall designate a medical director. If the medication-assisted treatment program is accredited by a Substance Abuse and Mental Health Services Administration (SAMHSA) approved accrediting body that meets nationally accepted standards for providing medication-assisted treatment, including the Commission on Accreditation of Rehabilitation Facilities (CARF) or the Joint Commission on Accreditation of Healthcare Organizations, then the program may designate a medical director to oversee all facilities associated with the accredited medication-assisted treatment program. The medical director shall be responsible for the operation of the medication-assisted treatment program, as further specified in the rules promulgated pursuant to this article. He or she may delegate the day to day operation of medication-assisted treatment program as provided in rules promulgated pursuant to this article. Within ten days after termination of a medical director, the medication-assisted treatment program shall notify the director of the identity of another medical director for that program. Failure to have a medical director practicing at the program may be the basis for a suspension or revocation of the program license. The medical director shall:

(1) Have a full, active and unencumbered license to practice allopathic medicine or surgery from the West Virginia Board of Medicine or to practice osteopathic medicine or surgery from the West Virginia Board of Osteopathic Medicine in this state and be in good standing and not under any probationary restrictions;

(2) Meet both of the following training requirements:

(A) If the physician prescribes a partial opioid agonist, he or she shall complete the requirements for the Drug Addiction Treatment Act of 2000; and

(B) Complete other programs and continuing education requirements as further described in the rules promulgated pursuant to this article;

(3) Practice at the licensed or registered medication-assisted treatment program a sufficient number of hours, based upon the type of medication-assisted treatment license or registration issued pursuant to this article, to ensure regulatory compliance and carry out those duties specifically assigned to the medical director as further described in the rules promulgated pursuant to this article;

(4) Be responsible for monitoring and ensuring compliance with all requirements related to the licensing and operation of the medication-assisted treatment program;

(5) Supervise, control and direct the activities of each individual working or operating at the medication-assisted treatment program, including any employee, volunteer or individual under contract, who provides medication-assisted treatment at the program or is associated with the provision of that treatment. The supervision, control and direction shall be provided in accordance with rules promulgated by the secretary; and

(6) Complete other requirements prescribed by the secretary by rule.

(d) Each medication-assisted treatment program shall designate counseling staff, either employee or those used on a referral-basis by the program, which meet the requirements of this article and the rules promulgated pursuant to this article. The individual members of the counseling staff shall have one or more of the following qualifications:

(1) A licensed psychiatrist;

(2) Certification as an alcohol and drug counselor;

(3) Certification as an advanced alcohol and drug counselor;

- (4) A counselor, psychologist, marriage and family therapist or social worker with a master's level education with a specialty or specific training in treatment for substance use disorders, as further described in the rules promulgated pursuant to this article;
- (5) Under the direct supervision of an advanced alcohol and drug counselor, a counselor with a bachelor's degree in social work or another relevant human services field: *Provided*, That the individual practicing with a bachelor's degree under supervision applies for certification as an alcohol and drug counselor within three years of the date of employment as a counselor; or
- (6) A counselor with a graduate degree actively working toward licensure or certification in the individual's chosen field under supervision of a licensed or certified professional in that field and/or advanced alcohol and drug counselor.
- (e) The medication-assisted treatment program shall be eligible for, and not prohibited from, enrollment with West Virginia Medicaid and other private insurance. Prior to directly billing a patient for any medication-assisted treatment, a medication-assisted treatment program must receive either a rejection of prior authorization, rejection of a submitted claim, or a written denial from a patient's insurer or West Virginia Medicaid denying coverage for such treatment: *Provided*, That the Secretary may grant a variance from this requirement pursuant to section six of this article. The program shall also document whether a patient has no insurance. At the option of the medication-assisted treatment program, treatment may commence prior to billing.
- (f) The medication-assisted treatment program shall apply for and receive approval as required from the United States Drug Enforcement Administration, Center for Substance Abuse Treatment or an organization designated by Substance Abuse and Mental Health and Mental Health Administration.
- (g) All persons employed by the medication-assisted treatment program shall comply with the requirements for the operation of a medication-assisted treatment program established within this article or by any rule adopted pursuant to this article.
- (h) All employees of an opioid treatment program shall furnish fingerprints for a state and federal criminal records check by the Criminal Identification Bureau of the West Virginia State Police and the Federal Bureau of Investigation. The fingerprints shall be accompanied by a signed authorization for the release of information and retention of the fingerprints by the Criminal Identification Bureau and the Federal Bureau of Investigation. The opioid treatment program shall be subject to the provisions of article forty-nine, chapter sixteen of this code and subsequent rules promulgated thereunder.
- (i) The medication-assisted treatment program shall not be owned by, nor shall it employ or associate with, any physician or prescriber:
- (1) Whose Drug Enforcement Administration number is not currently full, active and unencumbered;
 - (2) Whose application for a license to prescribe, dispense or administer a controlled substance has been denied by and is not full, active and unencumbered in any jurisdiction; or
 - (3) Whose license is anything other than a full, active and unencumbered license to practice allopathic medicine or surgery by the West Virginia Board of Medicine or osteopathic medicine or surgery by the West Virginia Board of Osteopathic Medicine in this state, and, who is in good standing and not under any probationary restrictions.
- (j) A person may not dispense any medication-assisted treatment medication, including a controlled substance as defined by section one hundred one, article one, chapter sixty-a of this code, on the premises of a licensed medication-assisted treatment program, unless he or she is a physician or pharmacist licensed in this state and employed by the medication-assisted treatment program unless the medication-assisted treatment program is a federally-certified narcotic treatment program. Prior to dispensing or prescribing medication-assisted treatment medications, the treating physician must access the Controlled Substances Monitoring Program database to ensure the patient is not seeking medication-assisted treatment medications that are controlled substances from multiple sources, and to assess potential adverse drug interactions, or both. Prior to dispensing

or prescribing medication-assisted treatment medications, the treating physician shall also ensure that the medication-assisted treatment medication utilized is related to an appropriate diagnosis of a substance use disorder and approved for such usage. The physician shall also review the Controlled Substances Monitoring Program database no less than quarterly and at each patient's physical examination. The results obtained from the Controlled Substances Monitoring Program Database shall be maintained with the patient's medical records.

(k) A medication-assisted treatment program responsible for medication administration shall comply with:

- (1) The West Virginia Board of Pharmacy regulations;
- (2) The West Virginia Board of Examiners for Registered Professional Nurses regulations;
- (3) All applicable federal laws and regulations relating to controlled substances; and
- (4) Any requirements as specified in the rules promulgated pursuant to this article.

(l) Each medication-assisted treatment program location shall be licensed separately, regardless of whether the program is operated under the same business name or management as another program.

(m) The medication-assisted treatment program shall develop and implement patient protocols, treatment plans or treatment strategies and profiles, which shall include, but not be limited by, the following guidelines:

(1) When a physician diagnoses an individual as having a substance use disorder, the physician may treat the substance use disorder by managing it with medication in doses not exceeding those approved by the United States Food and Drug Administration as indicated for the treatment of substance use disorders and not greater than those amounts described in the rules promulgated pursuant to this article. The treating physician and treating counselor's diagnoses and treatment decisions shall be made according to accepted and prevailing standards for medical care;

(2) The medication-assisted treatment program shall maintain a record of all of the following:

- (A) Medical history and physical examination of the individual;
- (B) The diagnosis of substance use disorder of the individual;
- (C) The plan of treatment proposed, the patient's response to the treatment and any modification to the plan of treatment;
- (D) The dates on which any medications were prescribed, dispensed or administered, the name and address of the individual for whom the medications were prescribed, dispensed or administered and the amounts and dosage forms for any medications prescribed, dispensed or administered;
- (E) A copy of the report made by the physician or counselor to whom referral for evaluation was made, if applicable; and
- (F) A copy of the coordination of care agreement, which is to be signed by the patient, treating physician and treating counselor. If a change of treating physician or treating counselor takes place, a new agreement must be signed. The coordination of care agreement must be updated or reviewed at least annually. If the coordination of care agreement is reviewed, but not updated, this review must be documented in the patient's record. The coordination of care agreement will be provided in a form prescribed and made available by the secretary;

- (3) Medication-assisted treatment programs shall report information, data, statistics and other information as directed in this code, and the rules promulgated pursuant to this article to required agencies and other authorities;
- (4) A physician, physician assistant, or advanced practice registered nurse shall perform a physical examination of a patient on the same day that the prescriber initially prescribes, dispenses or administers a medication-assisted treatment medication to a patient and at intervals as required in the rules promulgated pursuant to this article;
- (5) An alcohol and drug abuse counselor, an advanced alcohol and drug abuse counselor or other qualified counselor, psychiatrist, psychologist or social worker shall perform a biopsychosocial assessment, including, but not limited to, a mental status examination of a patient on the same day or no more than seven days prior to the day that the physician initially prescribes, dispenses or administers a medication-assisted treatment medication to a patient and at intervals as required in the rules promulgated pursuant to this article;
- (6) A prescriber authorized to prescribe a medication-assisted treatment medication who practices at a medication-assisted treatment program is responsible for maintaining the control and security of his or her prescription blanks and any other method used for prescribing a medication-assisted treatment medication. The prescriber shall comply with all state and federal requirements for tamper-resistant prescription paper. In addition to any other requirements imposed by statute or rule, the prescriber shall notify the secretary and appropriate law enforcement agencies in writing within twenty-four hours following any theft or loss of a prescription blank or breach of any other method of prescribing a medication-assisted treatment medication; and,
- (7) The medication-assisted treatment program shall have a drug testing program to ensure a patient is in compliance with the treatment strategy.”
- (n) Medication-assisted treatment programs shall only prescribe, dispense or administer liquid methadone to patients pursuant to the restrictions and requirements of the rules promulgated pursuant to this article.
- (o) The medication-assisted treatment program shall immediately notify the secretary, or his or her designee, in writing of any changes to its operations that affect the medication-assisted treatment program's continued compliance with the certification and licensure requirements.
- (p) If a physician treats a patient with more than sixteen milligrams per day of buprenorphine then clear medical notes shall be placed in the patient's medical file indicating the clinical reason or reasons for the higher level of dosage.
- (q) If a physician is not the patient's obstetrical or gynecological provider, the physician shall consult with the patient's obstetrical or gynecological provider to the extent possible to determine whether the prescription is appropriate for the patient.
- (r) A practitioner providing medication-assisted treatment may perform certain aspects telehealth if permitted under his or her scope of practice.
- (s) The physician shall follow the recommended manufacturer's tapering schedule for the medication assisted treatment medication. If the schedule is not followed, the physician shall document in the patient's medical record and the clinical reason why the schedule was not followed. The secretary may investigate a medication-assisted treatment program if a high percentage of its patients are not following the recommended tapering schedule.

<< WV ST § 16-5Y-6 >>

§ 16-5Y-6. Restrictions; variances and waivers.

- (a) A medication-assisted treatment program shall not be located, operated, managed or owned at the same location where a chronic pain management clinic licensed and defined in article five-h, chapter sixteen of this code is located.

(b) Medication-assisted treatment programs shall not have procedures for offering a bounty, monetary, equipment, or merchandise reward, or free services for individuals in exchange for recruitment of new patients into the facility.

(c) Medication-assisted treatment programs shall not be located within one-half mile of a public or private licensed day care center or public or private K–12 school.

Existing medication-assisted treatment programs, including both opioid treatment programs and office based medication-assisted treatment programs that are located within one-half mile of a public or private licensed day care center or public or private K–12 school, shall be granted a variance, provided that the facility demonstrates adequate patient population controls and that it may otherwise meet the requirements of this article and the rules promulgated pursuant to this article.

(d) The secretary may grant a waiver or a variance from any licensure or registration standard, or portion thereof, for the period during which the license or registration is in effect.

(1) Requests for waivers or variances of licensure or registration standards shall be in writing to the secretary and shall include:

(A) The specific section of this article or rules promulgated pursuant to this article for which a waiver or variance is sought;

(B) The rationale for requesting the waiver or variance;

(C) Documentation by the medication-assisted treatment program's medical director to the secretary that describes how the program will maintain the quality of services and patient safety if the waiver or variance is granted; and

(D) The consequences of not receiving approval of the requested waiver or variance.

(2) The secretary shall issue a written statement to the medication-assisted treatment program granting or denying a request for a waiver or variance of program licensure or registration standards.

(3) The medication-assisted treatment program shall maintain a file copy of all requests for waivers or variances and the approval or denial of the requests for the period during which the license or registration is in effect.

(4) The Office of Health Facility Licensure and Certification shall inspect each medication-assisted treatment program prior to a waiver or variance being granted, including a review of patient records, to ensure and verify that any waiver or variance request meets the spirit and purpose of this article and the rules promulgated pursuant to this article. The Office of Health Facility Licensure and Certification may verify, by unannounced inspection, that the medication-assisted treatment program is in compliance with any waiver or variance granted by the secretary for the duration of such waiver or variance.

<< WV ST § 16–5Y–7 >>

§ 16–5Y–7. Inspection; inspection warrant.

(a) The Office of Health Facility Licensure and Certification shall inspect each opioid treatment program annually, including a review of the patient records, to ensure that the program complies with this article and the applicable rules. A pharmacist, employed or contracted by the secretary, licensed in this state, and a law-enforcement officer may be present at each inspection.

(b) The Office of Health Facility Licensure and Certification shall perform unannounced complaint and verification inspections at office based medication-assisted treatment programs, including a review of the patient records, to ensure that the program complies with this article and the applicable rules. A pharmacist, employed or contracted by the secretary, licensed in this state and a law-enforcement officer may be present at each inspection.

(c) During an onsite inspection, the inspectors shall make a reasonable attempt to discuss each violation with the medical director or other owners of the medication-assisted treatment program before issuing a formal written notification.

(d) Any action taken to correct a violation shall be documented in writing by the medical director or other owners of the medication-assisted treatment program and may be verified by follow-up visits by the Office of Health Facility Licensure and Certification.

(e) Notwithstanding the existence or pursuit of any other remedy, the secretary may, in the manner provided by law, maintain an action in the name of the state for an inspection warrant against any person, partnership, association or corporation to allow any inspection or seizure of records in order to complete any inspection allowed by this article or the rules promulgated pursuant to this article, or to meet any other purpose of this article or the rules promulgated pursuant to this article.

(f) When possible, inspections for annual certification and licensure by the medication-assisted treatment programs will be done consecutively or concurrently. However, this provision does not limit the ability to conduct unannounced inspections pursuant to a complaint.

<< WV ST § 16-5Y-8 >>

§ 16-5Y-8. License and registration limitation; denial; suspension; revocation.

(a) The secretary may, by order, impose a ban on the admission of patients or reduce the patient capacity of the medication-assisted treatment program, or any combination thereof, when he or she finds upon inspection of the medication-assisted treatment program that the licensee or registrant is not providing adequate care under the medication-assisted treatment program's existing patient quota, and that a reduction in quota or imposition of a ban on admissions, or any combination thereof, would place the licensee or registrant in a position to render adequate care. Any notice to a licensee or registrant of reduction in quota or ban on new admissions shall include the terms of the order, the reasons therefor and the date set for compliance.

(b) The secretary shall deny, suspend or revoke a license or registration issued pursuant to this article if the provisions of this article or of the rules promulgated pursuant to this article are violated. The secretary may revoke a program's license or registration and prohibit all physicians and licensed disciplines associated with that medication-assisted treatment program from practicing at the program location based upon an annual, periodic, complaint, verification or other inspection and evaluation.

(c) Before any such license or registration is denied, suspended or revoked, however, written notice shall be given to the licensee or registrant, stating the grounds for such denial, suspension or revocation.

(d) An applicant, licensee or registrant has ten working days after receipt of the secretary's order denying, suspending or revoking a license or registration to request a formal hearing contesting such denial, suspension or revocation of a license or registration under this article. If a formal hearing is requested, the applicant, licensee or registrant and the secretary shall proceed in accordance with the provisions of article five, chapter twenty-nine-a of this code.

(e) If a license or registration is denied or revoked as herein provided, a new application for license or registration shall be considered by the secretary if, when and after the conditions upon which the denial or revocation was based have been corrected and evidence of this fact has been furnished. A new license or registration shall then be granted after proper inspection, if applicable, has been made and all provisions of this article and rules promulgated pursuant to this article have been satisfied.

(f) Any applicant, licensee or registrant who is dissatisfied with the decision of the secretary as a result of the hearing provided in this section may, within thirty days after receiving notice of the decision, petition the circuit court of Kanawha County, in term or in vacation, for judicial review of the decision.

(g) The court may affirm, modify or reverse the decision of the secretary and either the applicant, licensee or registrant, or the secretary may appeal from the court's decision to the Supreme Court of Appeals.

(h) If the license or registration of a medication-assisted treatment program is denied, suspended or revoked, the medical director of the program, any owner of the program or owner or lessor of the medication-assisted treatment program property shall cease to operate the clinic, facility, office or program as a medication-assisted treatment program as of the effective date of the denial, suspension or revocation. The owner or lessor of the medication-assisted treatment program property is responsible for removing all signs and symbols identifying the premises as a medication-assisted treatment program within thirty days. Any administrative appeal of such denial, suspension or revocation shall not stay the denial, suspension or revocation.

(i) Upon the effective date of the denial, suspension or revocation, the medical director of the medication-assisted treatment program shall advise the secretary and the Board of Pharmacy of the disposition of all medications located on the premises. The disposition is subject to the supervision and approval of the secretary. Medications that are purchased or held by a medication-assisted treatment program that is not licensed may be deemed adulterated.

(j) If the license or registration of a medication-assisted treatment program is suspended or revoked, any person named in the licensing or registration documents of the program, including persons owning or operating the medication-assisted treatment program, may not, as an individual or as part of a group, apply to operate another medication-assisted treatment program for up to five years after the date of suspension or revocation. The secretary may grant a variance pursuant to section six of this article to the prohibition of this subsection.

(k) The period of suspension for the license or registration of a medication-assisted treatment program shall be prescribed by the secretary, but may not exceed one year.

<< WV ST § 16-5Y-9 >>

§ 16-5Y-9. Violations; penalties; injunction.

(a) Any person, partnership, association or corporation which establishes, conducts, manages or operates a medication-assisted treatment program without first obtaining a license or registration as herein provided, or who violates any provisions of this article or any rule lawfully promulgated pursuant to this article, shall be assessed a civil penalty by the secretary in accordance with this subsection. Each day of continuing violation after conviction shall be considered a separate violation:

(1) If a medication-assisted treatment program or any owner or medical director is found to be in violation of any provision of this article, unless otherwise noted herein, the secretary may limit, suspend or revoke the program's license or registration;

(2) If the program's medical director knowingly and intentionally misrepresents actions taken to correct a violation, the secretary may impose a civil money penalty not to exceed \$10,000 and, in the case of any owner-operator medication-assisted treatment program, limit or revoke a medication-assisted treatment program's license or registration;

(3) If any owner or medical director of a medication-assisted treatment program concurrently operates an unlicensed or unregistered medication-assisted treatment program, the secretary may impose a civil money penalty upon the owner or medical director, or both, not to exceed \$5,000 per day;

(4) If the owner of a medication-assisted treatment program that requires a license or registration under this article fails to apply for a new license or registration for the program upon a change of ownership and operates the program under new ownership, the secretary may impose a civil money penalty upon the owner, not to exceed \$5,000; or

(5) If a physician operates, owns or manages an unlicensed or unregistered medication-assisted treatment program that is required to be licensed or registered pursuant to this article; knowingly prescribes or dispenses or causes to be prescribed or

dispensed, a medication-assisted treatment medication through misrepresentation or fraud; procures, or attempts to procure, a license or registration for a medication-assisted treatment program for any other person by making or causing to be made any false representation, the secretary may assess a civil money penalty of not more than \$20,000. The penalty may be in addition to or in lieu of any other action that may be taken by the secretary or any other board, court or entity.

(b) Notwithstanding the existence or pursuit of any other remedy, the secretary may, in the manner provided by law, maintain an action in the name of the state for an injunction against any person, partnership, association or corporation to restrain or prevent the establishment, conduct, management or operation of any medication-assisted treatment program or violation of any provision of this article or any rule lawfully promulgated thereunder without first obtaining a license or registration in the manner herein provided.

(c) In determining whether a penalty is to be imposed and in fixing the amount of the penalty, the secretary shall consider the following factors:

(1) The gravity of the violation, including the probability that death or serious physical or emotional harm to a patient has resulted, or could have resulted, from the medication-assisted treatment program's actions or the actions of the medical director or any practicing physician, the severity of the action or potential harm, and the extent to which the provisions of the applicable laws or rules were violated;

(2) What actions, if any, the owner or medical director took to correct the violations;

(3) Whether there were any previous violations at the medication-assisted treatment program; and

(4) The financial benefits that the medication-assisted treatment program derived from committing or continuing to commit the violation.

(d) Upon finding that a physician has violated the provisions of this article or rules adopted pursuant to this article, the secretary shall provide notice of the violation to the applicable licensing board.

<< WV ST § 16-5Y-10 >>

§ 16-5Y-10. Advertisement disclosure.

Any advertisement made by or on behalf of a medication-assisted treatment program through public media, such as a telephone directory, medical directory, newspaper or other periodical, outdoor advertising, radio or television, or through written or recorded communication, concerning the treatment of substance use disorders, as defined in section two of this article, shall include the name of, at a minimum, the medical director responsible for the content of the advertisement.

<< WV ST § 16-5Y-11 >>

§ 16-5Y-11. State Opioid Treatment Authority.

(a) Prior to establishing, operating, maintaining or advertising a medication-assisted treatment program within this state, a medication-assisted treatment program shall be approved by the state opioid treatment authority for operation of a medication-assisted treatment program in this state.

(b) The state opioid treatment authority shall act as the state's coordinator for the development and monitoring of medication-assisted treatment programs and it shall serve as a liaison with the appropriate federal agencies.

(c) The designated state oversight agency is responsible for licensing, monitoring and investigating complaints and grievances regarding medication-assisted treatment programs.

(d) The powers and duties of the state opioid treatment authority include, but are not limited to, the following:

(1) Facilitate the development and implementation of rules, regulations, standards and best practice guidelines to ensure the quality of services delivered by medication-assisted treatment programs;

(2) Act as a liaison between relevant state and federal agencies;

(3) Review medication-assisted treatment guidelines, rules, regulations and recovery models for individualized treatment plans of care developed by the federal government and other nationally recognized authorities approved by the secretary;

(4) Ensure delivery of technical assistance and informational materials to medication-assisted treatment programs as needed;

(5) Perform both scheduled and unscheduled site visits to medication-assisted treatment programs in cooperation with the identified state oversight agency when necessary and appropriate;

(6) Consult with the federal government regarding approval or disapproval of requests for exceptions to federal regulations, where appropriate;

(7) Review and approve exceptions to federal and state dosage policies and procedures;

(8) Receive and refer patient appeals and grievances to the designated state oversight agency when appropriate; and

(9) Work cooperatively with other relevant state agencies to determine the services needed and the location of a proposed medication-assisted treatment program.

<< WV ST § 16-5Y-12 >>

§ 16-5Y-12. Moratorium; certificate of need.

There is a moratorium on the licensure of new opioid treatment programs which do not have a certificate of need as of the effective date of the enactment of this section during the 2016 regular session of the Legislature which shall continue until the Legislature determines that there is a necessity for additional opioid treatment programs in West Virginia.

<< WV ST § 16-5Y-13 >>

§ 16-5Y-13. Rules; minimum standards for medication-assisted treatment programs.

(a) The secretary shall promulgate rules in accordance with the provisions of chapter twenty-nine-a of this code for the licensure of medication-assisted treatment programs to ensure adequate care, treatment, health, safety, welfare and comfort of patients at these facilities. These rules shall include, at a minimum:

(1) The process to be followed by applicants seeking a license;

(2) The qualifications and supervision of licensed and nonlicensed personnel at medication-assisted treatment programs and training requirements for all facility health care practitioners who are not regulated by another board;

(3) The provision and coordination of patient care, including the development of a written plan of care and patient contract;

- (4) The management, operation, staffing and equipping of the medication-assisted treatment program;
 - (5) The clinical, medical, patient and business records kept by the medication-assisted treatment program;
 - (6) The procedures for inspections and for review of utilization and quality of patient care;
 - (7) The standards and procedures for the general operation of a medication-assisted treatment program, including facility operations, physical operations, infection control requirements, health and safety requirements and quality assurance;
 - (8) Identification of drugs that may be used to treat substance use disorders that identify a facility as a medication-assisted treatment program;
 - (9) Any other criteria that identify a facility as a medication-assisted treatment program;
 - (10) The standards and procedures to be followed by an owner in providing supervision, direction and control of individuals employed by or associated with a medication-assisted treatment program;
 - (11) Data collection and reporting requirements;
 - (12) Criteria and requirements related to specific medication-assisted treatment medications; and
 - (13) Such other standards or requirements as the secretary determines are appropriate.
- (b) The Legislature finds that an emergency exists and, therefore, the secretary shall file an emergency rule to implement the provisions of this section pursuant to the provisions of section fifteen, article three, chapter twenty-nine-a of this code.

CHAPTER 60A. UNIFORM CONTROLLED SUBSTANCES ACT.

ARTICLE 9. CONTROLLED SUBSTANCES MONITORING.

<< WV ST § 60A-9-4 >>

§ 60A-9-4. Required information.

- (a) Whenever a medical services provider dispenses a controlled substance listed in Schedule II, III or IV as established under the provisions of article two of this chapter or an opioid antagonist, or whenever a prescription for the controlled substance or opioid antagonist is filled by: (i) A pharmacist or pharmacy in this state; (ii) a hospital, or other health care facility, for out-patient use; or (iii) a pharmacy or pharmacist licensed by the Board of Pharmacy, but situated outside this state for delivery to a person residing in this state, the medical services provider, health care facility, pharmacist or pharmacy shall, in a manner prescribed by rules promulgated by the board under this article, report the following information, as applicable:
- (1) The name, address, pharmacy prescription number and Drug Enforcement Administration controlled substance registration number of the dispensing pharmacy or the dispensing physician or dentist;
 - (2) The full legal name, address and birth date of the person for whom the prescription is written;
 - (3) The name, address and Drug Enforcement Administration controlled substances registration number of the practitioner writing the prescription;

- (4) The name and national drug code number of the Schedule II, III and IV controlled substance or opioid antagonist dispensed;
 - (5) The quantity and dosage of the Schedule II, III and IV controlled substance or opioid antagonist dispensed;
 - (6) The date the prescription was written and the date filled;
 - (7) The number of refills, if any, authorized by the prescription;
 - (8) If the prescription being dispensed is being picked up by someone other than the patient on behalf of the patient, the first name, last name and middle initial, address and birth date of the person picking up the prescription as set forth on the person's government-issued photo identification card shall be retained in either print or electronic form until such time as otherwise directed by rule promulgated by the board; and
 - (9) The source of payment for the controlled substance dispensed.
- (b) The board may prescribe by rule promulgated under this article the form to be used in prescribing a Schedule II, III, and IV substance or opioid antagonist if, in the determination of the board, the administration of the requirements of this section would be facilitated.
- (c) Products regulated by the provisions of article ten of this chapter shall be subject to reporting pursuant to the provisions of this article to the extent set forth in said article.
- (d) Reporting required by this section is not required for a drug administered directly to a patient by a practitioner. Reporting is, however, required by this section for a drug dispensed to a patient by a practitioner: *Provided*, That the quantity dispensed by a prescribing practitioner to his or her own patient may not exceed an amount adequate to treat the patient for a maximum of seventy-two hours with no greater than two seventy-two-hour cycles dispensed in any fifteen-day period of time.
- (e) The Board of Pharmacy shall notify a physician prescribing buprenorphine or buprenorphine/naloxone within sixty days of the availability of the an abuse deterrent form of buprenorphine or buprenorphine/naloxone is approved by the Food and Drug Administration as provided in FDA Guidance to Industry. Upon receipt of the notice, a physician may switch their patients using buprenorphine or buprenorphine/naloxone to the abuse deterrent form of the drug.

<< WV ST § 60A-9-5 >>

§ 60A-9-5. Confidentiality; limited access to records; period of retention; no civil liability for required reporting.

- (a)(1) The information required by this article to be kept by the board is confidential and not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovery in civil matters absent a court order and is open to inspection only by inspectors and agents of the board, members of the West Virginia State Police expressly authorized by the Superintendent of the West Virginia State Police to have access to the information, authorized agents of local law-enforcement agencies as members of a federally affiliated drug task force, authorized agents of the federal Drug Enforcement Administration, duly authorized agents of the Bureau for Medical Services, duly authorized agents of the Office of the Chief Medical Examiner for use in post-mortem examinations, duly authorized agents of licensing boards of practitioners in this state and other states authorized to prescribe Schedules II, III and IV controlled substances, prescribing practitioners and pharmacists and persons with an enforceable court order or regulatory agency administrative subpoena: *Provided*, That all law-enforcement personnel who have access to the Controlled Substances Monitoring Program database shall be granted access in accordance with applicable state laws and the board's legislative rules, shall be certified as a West Virginia law-enforcement officer and shall have successfully completed training approved by the board. All information released by the board must be related to a specific patient or a specific individual or entity under investigation by any of the above parties except that practitioners who prescribe or dispense controlled substances may request specific data related to their Drug Enforcement Administration controlled substance registration number or for

the purpose of providing treatment to a patient: *Provided, however,* That the West Virginia Controlled Substances Monitoring Program Database Review Committee established in subsection (b) of this section is authorized to query the database to comply with said subsection.

(2) Subject to the provisions of subdivision (1) of this subsection, the board shall also review the West Virginia Controlled Substance Monitoring Program database and issue reports that identify abnormal or unusual practices of patients who exceed parameters as determined by the advisory committee established in this section. The board shall communicate with practitioners and dispensers to more effectively manage the medications of their patients in the manner recommended by the advisory committee. All other reports produced by the board shall be kept confidential. The board shall maintain the information required by this article for a period of not less than five years. Notwithstanding any other provisions of this code to the contrary, data obtained under the provisions of this article may be used for compilation of educational, scholarly or statistical purposes, and may be shared with the West Virginia Department of Health and Human Resources for those purposes, as long as the identities of persons or entities and any personally identifiable information, including protected health information, contained therein shall be redacted, scrubbed or otherwise irreversibly destroyed in a manner that will preserve the confidential nature of the information. No individual or entity required to report under section four of this article may be subject to a claim for civil damages or other civil relief for the reporting of information to the board as required under and in accordance with the provisions of this article.

(3) The board shall establish an advisory committee to develop, implement and recommend parameters to be used in identifying abnormal or unusual usage patterns of patients in this state. This advisory committee shall:

(A) Consist of the following members: A physician licensed by the West Virginia Board of Medicine, a dentist licensed by the West Virginia Board of Dental Examiners, a physician licensed by the West Virginia Board of Osteopathic Medicine, a licensed physician certified by the American Board of Pain Medicine, a licensed physician board certified in medical oncology recommended by the West Virginia State Medical Association, a licensed physician board certified in palliative care recommended by the West Virginia Center on End of Life Care, a pharmacist licensed by the West Virginia Board of Pharmacy, a licensed physician member of the West Virginia Academy of Family Physicians, an expert in drug diversion and such other members as determined by the board.

(B) Recommend parameters to identify abnormal or unusual usage patterns of controlled substances for patients in order to prepare reports as requested in accordance with subsection (a), subdivision (2) of this section.

(C) Make recommendations for training, research and other areas that are determined by the committee to have the potential to reduce inappropriate use of prescription drugs in this state, including, but not limited to, studying issues related to diversion of controlled substances used for the management of opioid addiction.

(D) Monitor the ability of medical services providers, health care facilities, pharmacists and pharmacies to meet the twenty-four hour reporting requirement for the Controlled Substances Monitoring Program set forth in section three of this article, and report on the feasibility of requiring real-time reporting.

(E) Establish outreach programs with local law enforcement to provide education to local law enforcement on the requirements and use of the Controlled Substances Monitoring Program database established in this article.

(b) The board shall create a West Virginia Controlled Substances Monitoring Program Database Review Committee of individuals consisting of two prosecuting attorneys from West Virginia counties, two physicians with specialties which require extensive use of controlled substances and a pharmacist who is trained in the use and abuse of controlled substances. The review committee may determine that an additional physician who is an expert in the field under investigation be added to the team when the facts of a case indicate that the additional expertise is required. The review committee, working independently, may query the database based on parameters established by the advisory committee. The review committee may make determinations on a case-by-case basis on specific unusual prescribing or dispensing patterns indicated by outliers in the system or abnormal

or unusual usage patterns of controlled substances by patients which the review committee has reasonable cause to believe necessitates further action by law enforcement or the licensing board having jurisdiction over the practitioners or dispensers under consideration. The review committee shall also review notices provided by the chief medical examiner pursuant to subsection (h), section ten, article twelve, chapter sixty-one of this code and determine on a case-by-case basis whether a practitioner who prescribed or dispensed a controlled substance resulting in or contributing to the drug overdose may have breached professional or occupational standards or committed a criminal act when prescribing the controlled substance at issue to the decedent. Only in those cases in which there is reasonable cause to believe a breach of professional or occupational standards or a criminal act may have occurred, the review committee shall notify the appropriate professional licensing agency having jurisdiction over the applicable practitioner or dispenser and appropriate law-enforcement agencies and provide pertinent information from the database for their consideration. The number of cases identified shall be determined by the review committee based on a number that can be adequately reviewed by the review committee. The information obtained and developed may not be shared except as provided in this article and is not subject to the provisions of chapter twenty-nine-b of this code or obtainable as discovering in civil matters absent a court order.

(c) The board is responsible for establishing and providing administrative support for the advisory committee and the West Virginia Controlled Substances Monitoring Program Database Review Committee. The advisory committee and the review committee shall elect a chair by majority vote. Members of the advisory committee and the review committee may not be compensated in their capacity as members but shall be reimbursed for reasonable expenses incurred in the performance of their duties.

(d) The board shall promulgate rules with advice and consent of the advisory committee, in accordance with the provisions of article three, chapter twenty-nine-a of this code. The legislative rules must include, but shall not be limited to, the following matters:

- (1) Identifying parameters used in identifying abnormal or unusual prescribing or dispensing patterns;
 - (2) Processing parameters and developing reports of abnormal or unusual prescribing or dispensing patterns for patients, practitioners and dispensers;
 - (3) Establishing the information to be contained in reports and the process by which the reports will be generated and disseminated; and
 - (4) Setting up processes and procedures to ensure that the privacy, confidentiality, and security of information collected, recorded, transmitted and maintained by the review committee is not disclosed except as provided in this section.
- (e) Persons or entities with access to the West Virginia Controlled Substances Monitoring Program database pursuant to this section may, pursuant to rules promulgated by the board, delegate appropriate personnel to have access to said database.
- (f) Good faith reliance by a practitioner on information contained in the West Virginia Controlled Substances Monitoring Program database in prescribing or dispensing or refusing or declining to prescribe or dispense a schedule II, III, or IV controlled substance shall constitute an absolute defense in any civil or criminal action brought due to prescribing or dispensing or refusing or declining to prescribe or dispense.
- (g) A prescribing or dispensing practitioner may notify law enforcement of a patient who, in the prescribing or dispensing practitioner's judgment, may be in violation of section four hundred ten, article four of this chapter, based on information obtained and reviewed from the controlled substances monitoring database. A prescribing or dispensing practitioner who makes a notification pursuant to this subsection is immune from any civil, administrative or criminal liability that otherwise might be incurred or imposed because of the notification if the notification is made in good faith.

(h) Nothing in the article may be construed to require a practitioner to access the West Virginia Controlled Substances Monitoring Program database except as provided in section five-a of this article.

(i) The board shall provide an annual report on the West Virginia Controlled Substance Monitoring Program to the Legislative Oversight Commission on Health and Human Resources Accountability with recommendations for needed legislation no later than January 1 of each year.

<< WV ST § 60A–9–5a >>

**§ 60A–9–5a. Practitioner requirements to access database and
conduct annual search of the database; required rulemaking.**

(a) All practitioners, as that term is defined in section one hundred-one, article two of this chapter who prescribe or dispense Schedule II, III or IV controlled substances shall register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database: *Provided*, That compliance with the provisions of this subsection must be accomplished within thirty days of the practitioner obtaining a new license: *Provided, however*, That no licensing board may renew a practitioner's license without proof that the practitioner meet the requirements of this subsection.

(b) Upon initially prescribing or dispensing any pain-relieving controlled substance for a patient and at least annually thereafter should the practitioner or dispenser continue to treat the patient with controlled substances, all persons with prescriptive or dispensing authority and in possession of a valid Drug Enforcement Administration registration identification number and, who are licensed by the Board of Medicine as set forth in article three, chapter thirty of this code, the Board of Registered Professional Nurses as set forth in article seven, chapter thirty of this code, the Board of Dental Examiners as set forth in article four, chapter thirty of this code and the Board of Osteopathic Medicine as set forth in article fourteen, chapter thirty of this code shall access the West Virginia Controlled Substances Monitoring Program database for information regarding specific patients for whom they are providing pain-relieving controlled substances as part of a course of treatment for chronic, nonmalignant pain but who are not suffering from a terminal illness. The information obtained from accessing the West Virginia Controlled Substances Monitoring Program database for the patient shall be documented in the patient's medical record. A pain-relieving controlled substance shall be defined as set forth in section one, article three-a, chapter thirty of this code.

(c) The various boards mentioned in subsection (b) of this section above shall promulgate both emergency and legislative rules pursuant to the provisions of article three, chapter twenty-nine-a of this code to effectuate the provisions of this section.

<< WV ST § 60A–9–7 >>

§ 60A–9–7. Criminal penalties; and administrative violations.

(a) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who fails to do so as directed by the board is guilty of a misdemeanor and, upon conviction thereof, shall be fined not less than \$100 nor more than \$500.

(b) Any person who is required to submit information to the state Board of Pharmacy pursuant to the provisions of this article who knowingly and willfully refuses to submit the information required by this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than six months or fined not more than \$1,000, or both confined and fined.

(c) Any person who is required by the provisions of this article to submit information to the state Board of Pharmacy who knowingly submits thereto information known to that person to be false or fraudulent is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail not more than one year or fined not more than \$5,000, or both confined and fined.

(d) Any person granted access to the information required by the provisions of this article to be maintained by the state Board of Pharmacy, who shall willfully disclose the information required to be maintained by this article in a manner inconsistent with a legitimate law-enforcement purpose, a legitimate professional regulatory purpose, the terms of a court order or as otherwise expressly authorized by the provisions of this article is guilty of a misdemeanor and, upon conviction thereof, shall be confined in a county or regional jail for not more than six months or fined not more than \$1,000, or both confined and fined.

(e) Unauthorized access or use or unauthorized disclosure for reasons unrelated to the purposes of this article of the information in the database is a felony punishable by imprisonment in a state correctional facility for not less than one year nor more than five years or fined not less than \$3,000 nor more than \$10,000, or both imprisoned or fined.

(f) Any practitioner who fails to register with the West Virginia Controlled Substances Monitoring Program and obtain and maintain online or other electronic access to the program database as required in subsection (a), section five-a, article nine of this chapter, shall be subject to an administrative penalty of \$1,000 by the licensing board of his or her licensure. All such fines collected pursuant to this subsection shall be remitted by the applicable licensing board to the Fight Substance Abuse Fund created under section eight of this article. The provisions of this subsection shall become effective on July 1, 2016.

(g) Any practitioner or dispenser who is required to access the information contained in the West Virginia Controlled Substances Monitoring Program database as set forth in subsection (a), section five-a of this article and fails to do so as directed by the rules of his or her licensing board shall be subject to such discipline as the licensing board deems appropriate and on or after July 1, 2016, be subject to a \$100 administrative penalty per violation by the applicable licensing board. All such fines collected pursuant to this subsection shall be transferred by the applicable licensing board to the Fight Substance Abuse Fund created under section eight of this article.

(h) Lack of available internet connectivity is a defense to any action brought pursuant to subsections (d) or (f) of this section.

<< WV ST § 60A-9-8 >>

§ 60A-9-8. Creation of Fight Substance Abuse Fund.

There is hereby created a special revenue account in the state treasury, designated the Fight Substance Abuse Fund, which shall be an interest-bearing account. The fund shall consist of all moneys received from whatever source to further the purpose of this article. The fund shall be administered by the West Virginia Bureau for Public Health to provide funding for substance abuse prevention, treatment, treatment coordination, recovery and education. Any moneys remaining in the fund at the close of a fiscal year shall be carried forward for use in the next fiscal year. Fund balances shall be invested with the state's consolidated investment fund and any and all interest earnings on these investments shall be used solely for the purposes that moneys deposited in the fund may be used pursuant to this article. There is created within the Office of the Secretary of the Department of Health and Human Resources the Grant Writer Pilot Project. The Secretary shall hire a person as a grant writer, who shall be placed within the Office of the Secretary. This person shall identify, application and monitoring policies and procedures to increase grant applications and improve management and oversight of grants. The grant writer shall focus his or her abilities on obtaining grants concerning the prevention and treatment of substance abuse. The grant writer is not eligible for civil service. The department shall report to the Legislative Oversight Commission on Health and Human Resources Accountability on the implementation of the new grant policy; the number of grants obtained; and an analysis examining the costs associated with obtaining a grant verses the federal money received.

Approved March 29, 2016

Passed March 12, 2016; in effect 90 days from passage.